UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
Case No. 1:18-cv-181

NANCY SMITH,

Plaintiff,

v.

ALEX AZAR,
in his official capacity as
Secretary of the U.S. Department of
Health and Human Services,

Defendant.

ORIGINAL COMPLAINT

Plaintiff Nancy Smith files this Original Complaint and shows the Court as follows:

PARTIES

1. Plaintiff Nancy Smith is a natural person who resides in Rutherford College, Burke County, North Carolina.

2. Defendant Alex Azar is the Secretary of the Department of Health and Human Services, the department of the United States government responsible for the Medicare program and is being sued in only his official capacity.

JURISDICTION

3. This Court has subject matter jurisdiction under 42 U.S.C. §§ 405(g) and 1395ff(b) because this is an action arising after a final decision by the Secretary seeking review of that decision. The amount associated with plaintiff's claims is in excess of $1,600.

Accordingly, the amount in controversy requirements of 42 U.S.C. §1395ff(b)(1)(E) are satisfied.

4. Plaintiff's claims are timely pursuant to 42 U.S.C. §§ 405(g) and 1395ff(b) and 42 C.F.R. §§ 405.1130 and 405.1134 because the claims are brought within sixty days of the Secretary's final decisions.

VENUE

5. Venue is proper in this District pursuant to: 1) 42 U.S.C. §§ 405(g) and 1395ff(b) and 28 U.S.C. § 1391(e); and 2) 29 U.S.C. § 1391(b)(2) because a substantial portion of the violations alleged herein either occurred here or were directed towards plaintiffs in this District.

BACKGROUND

I. Diabetes and Continuous Glucose Monitoring (CGM's)

6. Many people with diabetes manage their disease by finger stick glucose monitoring and injections of insulin. However, a segment of the diabetic population cannot control their diabetes through conventional care. They suffer significant complications including stroke, loss of consciousness, and eye/kidney/nerve damage. Uncontrolled diabetes is the number one cause of kidney failure, non-traumatic lower limb amputations, and new cases of blindness among adults. Because of the significant public health costs, the Secretary urges individuals with diabetes to monitor and control their disease.

7. The peer-reviewed literature establishes that the longer an individual lives with diabetes,[1] the greater their chances are of developing "hypoglycemic/hyperglycemic unawareness," and the more erratic and more drastically their glucose levels will change ("brittle diabetes"). Individuals with diabetes and unawareness lack physical sensations (e.g., sweating or

[1] Although two types of diabetes exist, as used here, "diabetes" refers to Type I diabetes.

shakiness) that might alert them that their glucose is low or high to enable them to take corrective action. It is estimated that one in 20 individuals with diabetes dies each year in their sleep due to an undetected fatal low blood sugar. This is known as "dead in bed syndrome."[2] As a result of these and other factors, the life expectancy of an individual diagnosed with diabetes between 1950 and 1965 was 53.4 years.

8. A finger stick blood test indirectly measures blood glucose levels based on the amount of oxygen consumed in a reaction on a test strip which changes color (or causes an electric charge), and an algorithm may display a computed blood glucose level on a reader.

9. Similarly, a medical device known as a Continuous Glucose Monitor (hereafter, CGM) uses a needle that is inserted into interstitial fluid (i.e., the fluid that actually surrounds cells) and every five minutes (i.e., 288 times per day) computes and displays glucose levels.

10. Glucose in blood moves from the capillaries and into the interstitial fluid before being consumed by cells. Glucose values in the interstitial fluid are correlated with glucose values in blood itself. Thus, like a fingerstick, a CGM indirectly measures blood glucose levels which may be displayed on a screen or transmitted wirelessly to another device.

11. CGM alert patients of episodes of high glucose levels (hyperglycemia) and low glucose levels (hypoglycemia) so that patients can take action to control their blood glucose and avoid serious medical complications. They also provide trend information regarding how quickly glucose levels are dropping or rising.

12. The trend information is used by patients for the immediate short term management of their diabetes (*e.g.*, "Do I have time to make it to the lunch meeting or should I pull over now and drink juice?"), and are used by clinicians for the long term management of

[2] https://www.diapedia.org/acute-and-chronic-complications-of-diabetes/7105157816/dead-in-bed-syndrome (accessed June 14, 2017).

diabetes (*e.g.*, the patient is experiencing more frequent lows and extreme fluctuations in warm weather and thus should take higher and more frequent doses of glucose in summer months). CGMs have been the subject of multiple published peer-reviewed clinical studies, including large multi-center trials, all of which found improved clinical outcomes for patients who use a CGM.

II. The Plaintiff, Mrs. Nancy Smith

13. Plaintiff Nancy Smith is a 65 year-old wife, mother, and grandmother. Mrs. Smith is a lifelong resident of North Carolina and currently resides in Rutherford College, North Carolina where she lives with her husband, Gerald. Until prevented from doing so by her diabetic condition, Mrs. Smith was employed in the furniture industry for more than 25 years. Mrs. Smith is active in her church and enjoys spending time with her grandson.

14. First diagnosed with diabetes at the age of nine, Mrs. Smith has Type I diabetes with hypoglycemic unawareness. Before she was prescribed a CGM in about 2015, Mrs. Smith suffered hypoglycemic events resulting in a diabetic coma several times each month. As a result, Mrs. Smith suffered a high risk of injury or death. These events required revival of Mrs. Smith and transport to the emergency room by ambulance and immediate medical attention several times each month.

15. Since getting a CGM, Mrs. Smith has suffered very few/no hypoglycemic events.

16. Mrs. Smith's doctor, Dr. David Pillinger of Novant Health in Charlotte, has described Mrs. Smith's CGM as a "life saving measure" for Mrs. Smith and a "medical necessity."

III. Other Litigation Related to CGMs

17. In general, the Secretary has refused to cover CGMs on the grounds that a CGM is not durable medical equipment. National Coverage Determination (NCD) 280.1. This is so, the Secretary contends, because CGMs are not "primarily and customarily used for a medical purpose."

18. Instead, the Secretary contends that a CGM is excluded from coverage as "precautionary" – a non-statutory term. Although there was no national or local coverage determination (NCD/LCD) excluding CGM coverage, a local coverage article (LCA) described CGMs as excluded as "precautionary." LCA A52464.

19. The Secretary's refusal to cover CGMs has been the subject of numerous litigations.

20. At the Medicare Administrative Law Judge ("ALJ) level, through the filing of this Complaint, more than 40 ALJs have considered the Secretary's position that a CGM is not "primarily and customarily used for a medical purpose" and rejected that claim more than 55 times. A listing of relevant ALJ decisions may be found at http://dparrishlaw.com/wp-content/uploads/2017/11/Favorable-ALJs-on-CGM2.pdf.

21. With respect to the Secretary's effort to rely on/defer to the Article's description of CGM's as "precautionary" and, therefore, excluded, that was rejected as erroneous in *Whitcomb v. Burwell*, 2015 WL 3397697 (E.D. Wisc. May 26, 2015) (Duffin, J.) and *Finigan v. Burwell*, 189 F.Supp.3d 201 (D. Mass. 2016) (Young, J.). In both cases, the district court held that reliance on/deference to the Article was erroneous.

22. As to the Secretary's base position that a CGM is not "primarily and customarily used for a medical purpose", that position has been rejected by three district courts.

23. In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.) and *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.) the district courts found that the Secretary's claim that a CGM is not "primarily and customarily used for a medical purpose" was erroneous, not supported by substantial evidence, and in each case, ordered the Secretary to provide CGM coverage.

24. Further, in the *Whitcomb* case, the court found that the Secretary's position "arbitrary and capricious" and "unreasonable." Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.) at 14, 12.

25. On Ms. Whitcomb's motion for fees under the Equal Access to Justice Act, the court found that the Secretary's position was not substantially justified. *See Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. June 12, 2018) (Jones, J). Further, the court found that a "special factor" was present and awarded Ms. Whitcomb her attorney's fees at their usual and customary billing rate.

26. Overall, the *Whitcomb* court awarded more than $70,000 in attorney's fees under EAJA. *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. June 12, 2018) (Jones, J) at 2.

27. Likewise, the Secretary's own Civil Remedies Division concluded that exclusion of CGM coverage on the grounds that a CGM is "precautionary" did not pass the "reasonableness standard." *See* DAB No. CR4596, 2016 WL 2851236 at *18.

IV. Exhaustion of Administrative Remedies\Review

28. Two Medicare Appeals Council decisions are at issue in this case (collectively the "Decisions").

A. M-17-8596 (May 11, 2018)

29. Mrs. Smith received Dexcom G4 transmitters and sensors on July 11 and November 10, 2016. Mrs. Smith's claim for coverage was denied, then denied again on redetermination, then denied again on reconsideration. These denials were founded on the claim that a CGM is "precautionary." Mrs. Smith appealed.

30. On August 16, 2017, ALJ Raff issued a decision denying Mrs. Smith's request for coverage. *See* Decision for ALJ Appeal No. 1-6376101653. Judge Raff found that Mrs. Smith's "medical need for a CGM device is clear" (ALJ Decision at 1), that a CGM "has been extremely helpful" to Mrs. Smith (ALJ Decision at 2), and that Mrs. Smith "has received significant medical benefit" from using a CGM (ALJ Decision at 8).

31. Nevertheless, Judge Raff concluded that the Article precluded coverage as "precautionary" and that he was "bound" by CMS Ruling 1682R (which issued in January 2017 and applied to services after that date) which limited coverage to "therapeutic" CGMs (i.e., CGMs that were "non-precautionary") and that although the Dexcom G5 would have been covered, the Dexcom G4 was not covered. Mrs. Smith appealed.

32. On May 11, 2018, the MAC denied Mrs. Smith's appeal (the "May 11 Decision"). There, the MAC again contended that CGMs are not "primarily and customarily used for a medical purpose" because they are "precautionary." Further, the MAC contended that the negative district court decisions were wrong and, in any event, the district courts should defer to

the Secretary's greater wisdom/authority under *Chevron*. "May 11 Decision" M-17-8596 at 10, 12.

B. M-17-3301 (May 14, 2018)

33. Mrs. Smith received a prescription for a Dexcom G4 CGM device and on April 14, 2016, submitted a claim for the same. Mrs. Smith's claim for coverage was denied, then denied again on redetermination, then denied again on reconsideration. These denials were founded on the claim that a CGM is "precautionary." Mrs. Smith appealed.

34. On December 1, 2016, ALJ Gulin denied Mrs. Smith's claim. Judge Gulin held that coverage was precluded because the Article described CGMs as "precautionary."

35. On May 14, 2018, the MAC denied Mrs. Smith's appeal on the same grounds as in the May 11 Decision, M-17-8596.

V. A CGM is Durable Medical Equipment

36. A CGM can withstand repeated use.

37. A CGM is primarily and customarily used to serve a medical purpose.

38. A CGM is generally not useful to a person in the absence of illness or injury.

39. A CGM is appropriate for use in a patient's home.

CAUSES OF ACTION

Count I
Arbitrary and Capricious and Unsupported by Substantial Evidence Under the APA
(a CGM is Medically Necessary Medical Equipment for Type 1 Diabetes)

40. Paragraphs 1-39 are incorporated as if fully set forth here.

41. Under the Medicare statute, 42 U.S.C. §1395ff(b), the final agency decision included in this action is subject to judicial review. Under the APA, the reviewing court shall set

aside the final agency decision if, *inter alia,* it is contrary to law, arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence in the record.

42. To the extent that the Secretary's Decisions in this action found that a CGM and its related supplies are precautionary and do not serve a medical purpose and are therefore not reasonable and medically necessary, the Secretary's decisions must be set aside because they are contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record.

43. Further, to the extent that the Secretary's Decisions in this action found that a CGM and its related supplies are not durable medical equipment and therefore not reasonable and medically necessary, the Secretary's decisions must be set aside because they are contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record.

44. A CGM is recognized nationally and internationally by clinicians, researchers, and payers, as a reasonable and medically necessary medical device which has become the standard of care for individuals suffering from Type 1 diabetes with hypoglycemic unawareness.

45. The FDA has approved CGMs as a safe and effective medical device and it is prescribed by a physician.

46. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions and issue an order finding that the Mrs. Smith's CGM is not precautionary and is reasonable and medically necessary for Ms. Smith, and direct the Secretary to make appropriate payment for the claims that are the subject of this case.

Count II
Arbitrary and Capricious and Unsupported by Substantial Evidence Under the APA
(The Decisions Are Contrary to the Secretary's Other Determinations)

47. Plaintiff hereby incorporates by reference paragraphs 1 to 46 herein.

48. Under the Medicare statute, 42 U.S.C. §1395ff(b), the final agency decisions included in this action are subject to judicial review. Under the APA, the reviewing court shall set aside the final agency decision if, *inter alia,* it is contrary to law, arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence in the record.

49. To the extent that the Secretary's Decisions in this action found that a CGM and its related supplies are precautionary and therefore not covered under the Medicare durable medical benefit, the Secretary's Decisions must be set aside because they are contrary to law and arbitrary and capricious, an abuse of discretion and not supported by substantial evidence.

50. The Secretary repeatedly has determined a CGM is durable medical equipment covered under the Medicare DME benefit and is reasonable and medically necessary for other Medicare beneficiaries suffering from Type 1 diabetes with hypoglycemic unawareness.

51. Based on the foregoing, the Secretary's Decisions are contrary to Medicare regulations, arbitrary and capricious, and unsupported by substantial evidence in the record, and Plaintiff asks the Court to reverse the Secretary's Decisions and issue an order finding that the CGM is reasonable and medically necessary for Mrs. Smith, and direct the Secretary to make appropriate payment for the transmitter and sensors for the device that are the subject of this case.

Count III
Violation of APA as Contrary to Law
(The Decisions Are Contrary to the Act, NCDs, and Regulations)

52. Plaintiff hereby incorporates by reference paragraphs 1 to 51 herein.

53. The Secretary's Decisions in this action must be set aside because they are contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record.

54. The Secretary's findings that CGM is precautionary and not primarily medical, not DME and not covered by Medicare, are contrary to Section 1861(n) of the Act and the Secretary's determinations reflected in NCD 280.1 which provide national coverage for glucose monitors.

55. Further, to the extent the Secretary deems CGM not to be DME, that finding is inconsistent with the regulatory DME definition cited in his Decisions.

56. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions as contrary to law, as arbitrary, capricious and unsupported by the evidence, and issue an order finding that the CGM and its related supplies are eligible for coverage under the Act, NCD 280.1, and Medicare regulations, and reasonable and medically necessary for Ms. Smith.

Count IV
Contrary to Law Under the APA
(Improper Deference to an Article)

57. Plaintiff hereby incorporates by reference paragraphs 1 to 56 herein.

58. To the extent that the Secretary's Decisions are premised on giving deference to an Article, which is not an LCD and is not entitled to deference, the Secretary's Decisions must be set aside because they are contrary to law, regulation and arbitrary and capricious, and not supported by substantial evidence.

59. The Secretary provided no basis for giving deference to an Article, declining to follow the NCDs, or acknowledging that even if the Article applied, it should not be given deference in view of Mrs. Smith's uncontested dire need for a CGM to avoid life-endangering glucose swings.

60. The Secretary provided no basis for applying the Article which has been found not supported by clinical and scientific evidence.

61. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Decisions and issue an order finding that the Secretary's deference to an Article was contrary to law, arbitrary and capricious and unsupported by substantial evidence, and that a CGM and its related supplies are reasonable and medically necessary for Mrs. Smith, and order the Secretary to make payment on the claims at issue and any future claims for Mrs. Smith's CGM and supplies.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests:

A. An order finding the Secretary's denials erroneous, arbitrary and capricious, unreasonable, and not supported by substantial evidence.

B. An order setting aside the Secretary's decisions denying coverage and remanding each claim to the Secretary pursuant to the Fourth Sentence of 42 U.S.C. § 405(g) with instruction to cover Mrs. Smith's CGM equipment and supplies;

C. An order that the Court will retain jurisdiction over the decisions at issue until payment of the claims at issue has been completed;

D. An order awarding Plaintiff's attorneys' fees and costs incurred in this litigation, including under the Equal Access to Justice Act, 28 U.S.C. § 2412(b) and (d).

E. Such other and further relief as the Court may deem appropriate.

Date: June 28, 2018

Respectfully submitted,

/s/Edward G. Connette
EDWARD G. CONNETTE

N.C. Bar No. 9172
EConnette@essexrichards.com

/s/Norris A. Adams, II
NORRIS A. ADAMS, II
N.C. Bar No. 32552
nadams@essexrichards.com
ESSEX RICHARDS, P.A.
1701 South Blvd
Charlotte, NC 28203
Ph (704) 377-4300
Fax (704) 372-1357

PARRISH LAW OFFICES

Debra Parrish*
James Pistorino*
Bridget Noonan*
788 Washington Road
Pittsburgh, PA 15228
TEL 412-561-6250
FAX 412-561-6253
Email Debbie@dparrishlaw.com

Attorneys for Plaintiff

*Subject to Admission Pro Hac Vice